PFIZER & MODERNA COVID-19 VACCINES

• VACCINE SAFETY
• VACCINE EFFICACY
• FOLLOW-UP FOR SAFETY AND EFFICACY

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Sandra P. Chang, PhD, John A. Burns School of Medicine, UH Manoa
DOH MEDICAL ADVISORY GROUP CO-CHAIRS
AN ARRAY OF VACCINES

<table>
<thead>
<tr>
<th>Virus</th>
<th>Viral vector</th>
<th>Nucleic acid</th>
<th>Protein-based</th>
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<tr>
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<td>Replicating</td>
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<tr>
<td>Weakened</td>
<td>Non-replicating</td>
<td>RNA</td>
<td>Virus-like particles</td>
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* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.
How mRNA vaccines work

Genetic instructions are given to the immune system to recognise the virus

Scientists focus on the genetic sequence for the virus’s ‘spike’ protein. This is used to synthesise an mRNA sequence – instructions that cells can use to make the ‘spike’ protein

The synthetic mRNA is packaged in a lipid nanoparticle that delivers the instructions to a cell

Once inside the cell, its cellular machinery follows the mRNA instructions to produce the viral protein. This is displayed on the surface of the cell and stimulates an immune system response

Source: Pfizer
Update on COVID-19 Vaccine Development

**Pfizer/BioNTech BNT162b2 Vaccine**

- mRNA COVID-19 vaccine
  - 2 dose injection, 21 days apart
- Phase 3 clinical trial began July 27, 2020
- Well-tolerated with most adverse effects resolving shortly after vaccination
- **95% effective** (170 confirmed COVID-19 cases)
  - 162 cases in placebo group
  - 8 cases in vaccine group
- FDA EUA approved: Dec. 10, 2020
- FDA BLA submission anticipated in Q2 2021

**Moderna mRNA 1273 Vaccine**

- mRNA COVID-19 vaccine
  - 2 dose injection, 28 days apart
- Phase 3 clinical trial began July 27, 2020
- Generally well-tolerated with majority of adverse effects mild to moderate and resolving within 2-3 d
- **94.1% effective** (196 confirmed COVID-19 cases)
  - 185 cases in placebo group
  - 11 cases in vaccine group
- FDA EUA review: Dec. 17, 2020
- FDE EUA approved: Dec. 18, 2020
Vaccine Trial Participant Diversity

- Vaccine Trials Included Individuals of Diverse Ethnicities and High-risk Age Groups

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<th>Moderna</th>
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<td>Age &gt;=65 y</td>
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ADVANCED MANUFACTURING

Process Dev  Scale-up  Validate  Large Scale Production

DISCOVERY & PRECLINICAL DEVELOPMENT

SARS-CoV-2 Genetic Sequence  Animal Studies

CLINICAL GLOBAL PHASE 1/2/3 TRIAL

Phase 1  Pivotal Phase 2 / 3

In addition, Phase 1 in Germany  ~44,000 people above 12 years of age

Weekly Data Monitoring Committee Reviews

JAN 2020  MAR  APR  JUL

Pfizer/BioNTech Letter of Intent Signed March 17, 2020

Candidate/Dose Selection BNT162b2 July 24, 2020

EUA Submission November 20, 2020

Potential BLA Submission Goal: Q2 2021
Pfizer Phase 2/3 Trial Design

BNT162b2 mRNA vaccine, IM injection, 0 & 21 d
44,000 Study Participants: 266 children ages 12-15 y, 608 children ages 16-17 y, 43,518 adults ≥ 18 y
50% vaccine, 50% placebo

Primary Efficacy Endpoint:
Confirmed COVID-19 7 d after second dose to end of study (2 y)
Without previous infection
With or without previous infection

Confirmed COVID-19: acute respiratory illness + positive NAAT for SARS-CoV 2
Primary Efficacy Endpoint: 164 cases of confirmed COVID-19 for true VE rate ≥ 60%
Pfizer Phase 2/3 Trial Design

Secondary Efficacy Endpoints

• Confirmed COVID-19 from 14 d after Dose 2
• Severe COVID-19 from 7 d or 14 d after Dose 2
• CDC-defined COVID-19 from 7 d or 14 d after Dose 2
Pfizer Vaccine Efficacy

**Primary objective analysis**

- Vaccine efficacy rate of 95% against confirmed COVID-19
  - Participants without prior COVID-19 infection 7 d after 2\(^{nd}\) dose
  - Participants with and without prior COVID-19 infection 7 d after 2\(^{nd}\) dose
- Vaccine efficacy rate 94% in adults over 65 years of age
- Efficacy appears consistent across age, gender, race and ethnicity demographics
- Continued collection of subgroup data needed over full, 2-year study period

**Secondary objective analysis**

- Vaccine efficacy against severe COVID-19
  - 9 cases in placebo group vs. 1 case in vaccinated group
- Vaccine efficacy in preventing COVID-19 after first dose
- Vaccine efficacy in preventing COVID-19 in individuals with prior SARS-CoV-2 infection
- More data needed to firmly support these secondary objectives
Pfizer Vaccine Safety

- Participants followed for a median of 2 months following 2nd dose of vaccine:
  - Solicited safety data: randomized subset of 8,000 participants 18 years and older, ~100 children 12-15 years of age
  - Unsolicited safety data: 38,000 trial participants
- Vaccine well tolerated with most solicited adverse events (SAE) resolving shortly after vaccination (2-3 d)
  - Most common SAEs: injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever
  - Few Grade 3 SAEs greater than or equal to 2% in frequency that prevent daily routine activity: fatigue, headache
  - Older adults (>55 y) reported fewer and milder SAE following vaccination
  - Few cases of lymphadenopathy & Bell’s Palsy requires further surveillance
  - Similar safety profile across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, participants with or without evidence of prior SARS-CoV-2 infection at enrollment
    - Will continue to collect subgroup data for remainder of 2-year study

US FDA safety milestones achieved for EUA
Moderna Phase 3 Trial Design

mRNA-1273 vaccine, IM injection
1 & 29 d
30,418 Study Participants: adults 18 y of age or older (58% < 65 y, not at risk; 42% ≥ 65 y or at increased risk of complications)
50% vaccine, 50% placebo

Primary Efficacy Outcomes:
COVID-19 14 d after second dose

COVID-19 case definition:
• At least TWO of defined **systemic symptoms**, OR
• At least ONE of defined **respiratory signs/symptoms**, AND
• At least one **positive SARS-CoV-2 NAA test**

Primary Efficacy Endpoint: 151 cases of confirmed COVID-19 for true VE rate ≥ 60%
COVID-19 active surveillance throughout the study
Daily telemedicine visits for participants with COVID-19
eDiary captures solicited local and systemic adverse reactions in all participants
SAEs and MAAEs captured throughout the study
Moderna Phase 3 Trial Design

Secondary Efficacy Outcomes

- Severe COVID-19
- Serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity
- COVID-19 using a secondary definition of symptoms
- Death caused by COVID-19
- COVID-19 after the first dose of vaccine
- Asymptomatic SARS-CoV-2 infection
- COVID-19 regardless of prior SARS-CoV-2 infection
Moderna Vaccine Efficacy

Primary endpoint analysis

- Vaccine efficacy rate (VE) of 94.1% against confirmed COVID-19 (overall)
  - Participants without history of prior COVID-19 infection 14 d after second dose
- VE of 86.4% against confirmed COVID-19, 65 y or older
- VE of 90.9% against confirmed COVID-19, participants at high risk for severe disease
- Efficacy consistent across age, race, ethnicity, gender demographics
Moderna Vaccine Efficacy

Secondary endpoint analysis

- Vaccine efficacy rate of 100% against severe COVID-19 cases
- 30 cases of severe COVID-19 in placebo group (including 1 death)
- No cases of severe COVID-19 in vaccinated group
- Preliminary evidence for prevention of Asymptomatic Infection after 1st dose
- Asymptomatic infection measured by SARS-CoV-2 NAAT prior to 2nd injection in healthy/asymptomatic participants

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<th>mRNA-1273 Vaccine, N=14,134</th>
<th>Placebo, N=14,073</th>
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<tr>
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<tr>
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Moderna Vaccine Safety

• Solicited adverse events indicate vaccine was well-tolerated
• Majority of adverse events mild or moderate in severity
  • First dose – injection site pain, lymphadenopathy
  • Second dose – fatigue, myalgia, arthralgia, fever, headache, chills, nausea/vomiting, lymphadenopathy, pain and erythema/redness at injection site
• Grade 3 SAEs (frequency greater than or equal to 2%) generally short-lived (Gr. 3: severe = prevents daily routine activity)

US FDA safety milestones achieved for EUA
Moderna Vaccine Safety

• No anaphylactic or severe hypersensitivity reactions with close temporal relation to vaccination
  • Will monitor for severe allergic reactions during public vaccination

• Pregnancy
  • Animal studies of developmental and perinatal/postnatal reproductive toxicity study found no adverse effects on female reproduction, fetal/embryonic development, or permanent postnatal developmental effects

• Small number of cases of Bell’s palsy, lymph node swelling – need for monitoring with more widespread use of vaccine
Vaccine Safety & Efficacy Follow-up

• Both Pfizer and Moderna will continue safety and efficacy data collection for 2 years after study initiation
• Follow-up in progress for small number of reports of anaphylaxis in UK and US
  • US: 6 cases of severe allergic reactions per 272,000 vaccinations (0.002%)
  • UK: 2 confirmed cases of severe allergic reactions per 130,000 vaccinations (0.0015%)
Vaccine Safety & Efficacy Follow-up

• Questions to be answered with additional data from ongoing trials:
  • How long will the vaccine last (duration of protection)?
  • Will vaccination prevent asymptomatic SARS-CoV-2 infection?
  • Will vaccination reduce SARS-CoV-2 transmission?
  • Are two vaccine doses required for protection or can protection be achieved with a single vaccine dose?
  • Is the vaccine safe and effective in children 12-15 years of age? In pregnant women?

• Bridging studies are under consideration to demonstrate safety/immunogenicity in young children and pregnant and lactating women not included in current trials.
CDC/FDA Vaccine Safety Follow-up

• Active Surveillance
  • **v-safe** after vaccination health checker app

• Passive Surveillance
  • CDC/FDA Vaccine Adverse Event Reporting System (VAERS)
    • Long-standing, established vaccine safety monitoring system

• Individual Case Consults
  • CDC Clinical Immunization Safety Assessment Project

• Large-linked database monitoring
GET VACCINATED WHEN IT'S YOUR TURN
Resources

• Pfizer/BioNTech SARS-CoV-2 Vaccine Clinical Trial Protocol
• Pfizer Press Release on Final Efficacy Analysis of Phase 3 Study, 11/18/20
• Moderna SARS-CoV-2 Vaccine Clinical Trial Protocol
• Moderna Press Release on First Interim Analysis of Phase 3 Study, 11/16/20
• Moderna Press Release on Final Efficacy Analysis of Phase 3 Study, 11/30/20
• FDA Briefing Document: Moderna COVID-19 Vaccine, 12/17/20
• ACIP Post-authorization safety monitoring update, 12/01/20
JABSOM COVID-19 Vaccine Update:
Prioritization, Allocation, Logistics

December 21, 2020

Lee Buenconsejo-Lum, MD, FAAFP
Associate Dean for Academic Affairs
John A. Burns School of Medicine
Member of numerous State Vaccine Implementation Plan committees
JABSOM Liaison to HI EMA S ESF-8

https://hawaiicovid19.com/vaccine/
Operational Phases

- **Phase 1**: Potentially Limited Doses Available
- **Phase 2**: Large Number of Doses Available, Supply Likely to Meet Demand
- **Phase 3**: Likely Sufficient Supply, Slowing Demand

*Figure ES-5: Operational Phases*

- Phase 1 started 12/15/20
- Phase 2 ?? March
- Phase 3 ?? May-June
# Update on Vaccine Development

## November 20 & 30
- Pfizer submits EUA application 11/20
- Moderna submits EUA on 11/30
- AstraZeneca could also submit EUA in December

## December 1
- CDC ACIP met to discuss prioritization allocation strategies
- Revised stages slightly
- Balancing risk of infection and risk of death

## December 10-12
- FDA EUA Dec 11
- ACIP approval Dec 12

## December 14-16
- First shipments arrive to HI
- HPH, Queen’s, Kaiser started 12/15

## December 14
- 1st Exercise at LCC for CCHNL First responders
- Operations plans being developed

## December 17-20
- FDA EUA 12/18; ACIP approval 12/19
- ACIP recs on phased allocation of 1b, 1c on 12/20
ACIP Phased Allocation of COVID-19 Vaccines

Work Group Considerations:
Goals of the COVID-19 Vaccine Program

- Ensure safety and effectiveness of COVID-19 vaccines
- Reduce transmission, morbidity, mortality of COVID-19 disease
- Help minimize disruption to society and the economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution
ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution.

Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable.

Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical.

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.
## Work Group considerations: Balancing Goals

<table>
<thead>
<tr>
<th>Prevention of Morbidity &amp; Mortality</th>
<th>Preservation of Societal Functioning</th>
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</thead>
<tbody>
<tr>
<td>1a LTCF residents</td>
<td>Health care personnel</td>
</tr>
<tr>
<td>1b Persons 75 years and older</td>
<td>Frontline Essential Workers</td>
</tr>
<tr>
<td>1c Persons 65-74 years</td>
<td>Other Essential Workers</td>
</tr>
<tr>
<td>Persons 16+4 with high-risk medical conditions</td>
<td></td>
</tr>
</tbody>
</table>

- Ensure safety and effectiveness of COVID vaccines
- Ensure equity in vaccine allocation and distribution
## NASEM Framework

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
</table>
| **Phase 1a “Jumpstart Phase”**  
• High-risk health workers  
• First responders  
  |  
| **Phase 1b**  
• People of all ages with comorbid and underlying conditions that put them at *significantly* higher risk  
• Older adults living in congregate or overcrowded settings  
  |  
| **Phase 2**  
• K-12 teachers and school staff and child care workers  
  |  
| • Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and substantially higher risk of exposure  
  |  
| • People of all ages with comorbid and underlying conditions that put them at *moderately* higher risk  
  |  
| • People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, development and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings  
  |  
| • People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings  
  |  
| • All older adults not included in Phase 1  
  |  
| • Young adults  
  |  
| • Children  
  |  
| • Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2  
  |  

DHS CISA Essential Workers

- The following list of identified essential critical infrastructure workers is intended to be *overly inclusive* reflecting the diversity of industries across the United States.
Essential Workers* (total ~87M)

Frontline Essential Workers (~30M)
- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

Other Essential Workers (~57M)
- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

Work Group Proposed Interim Phase 1 Sequence

Phase 1c
Adults with high-risk medical conditions
Adults 65+

Phase 1b
Essential workers
(examples: Education Sector, Food & Agriculture, Utilities, Police, Firefighters, Corrections Officers, Transportation)

Phase 1a
Health care personnel
LTCF residents

Time
ACIP 12/19/20 (1B & 1C)

Proposed Phases of COVID-19 Vaccination

<table>
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<tr>
<th>Phase 1a</th>
<th>Phase 1b</th>
<th>Phase 1c</th>
<th>Phase 2</th>
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</thead>
</table>

Hawai`i Prioritization/Allocation WG meets 12/23/20 to further refine for Hawai`i
Factors that impacted the modeling and ACIP recommendations for 1B and 1C

• COVID-19 incidence is highest in young adults
  • 18-29 (US)
  • 85+ 2nd highest per capita (US)

• Mortality rates are highest in older adults

• Proportion of all causes and deaths involving COVID is similar age 45-85 (9-11%)

• Adults 75+ account for 25% of hospitalizations
  • 55-74 = 39% of hospitalizations
  • Hospitalization rates highest in older adults
  • Risk of in-hospital death increases with age

• Risk increases with # of underlying conditions
  • 2.5 → 4.5 → 5.0 x adjusted rate ratio

• High seroprevalence among many frontline essential worker groups in NYC (May-July 2020)
Summary of Work Group interpretation: Modeling

- In the scenarios considered, differences between strategies is minimal
  - Vaccinating older adults first averts slightly more deaths, vaccinating younger adults first (essential workers or younger adults with high-risk conditions) averts slightly more infections
  - Ethical principles and implementation considerations also contribute to selecting the optimal sequence in Phase 1b and 1c

- Largest driver of impact in averted deaths and infections is the timing of vaccine introduction in relation to increases in COVID-19 cases
  - Emphasizes the need to continue non-pharmaceutical interventions (e.g. wearing a mask, social distancing to prevent cases so vaccine can have maximum impact)

- Vaccine’s ability to prevent transmission will further inform future modeling analysis and interpretation

Sub-Prioritization Considerations – 4 Criteria in Current Plan

**Risk of acquiring infection**
- Immune compromise
- Aerosolizing procedures
- Frequent contact with COVID + patients
- Job cannot maintain 6’ distance from many people/day
- Prolonged contact with >10 people/day
- Contact with persons who may refuse or are unable to wear a mask
- Live or work in a congregate living setting
- Exposure to bodily fluids

**Risk of severe illness**
- Immune compromise
- Age > 65
- Underlying Medical Conditions
- From a disproportionately affected community
- Smoker

**Risk of societal impact**
- Direct patient care or critical support service
- First responder with direct public contact or critical support function
- Other critical worker in high risk
- Live with someone who is a healthcare worker, first responder, or other critical worker
- Sole income source for household

**Risk of spread of COVID**
- Direct patient contact
- First responder with direct public contact
- Frequent contact where you cannot maintain 6’ distance
- Frequent prolonged contact (>15 minutes/person) < 6’ distance
- Live with more than 3 other individuals
- Live with someone who has any of the risks for severe illness or mortality
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<td><strong>Total</strong></td>
<td>76,547</td>
<td>66,318</td>
<td></td>
<td>31</td>
<td>369,396</td>
<td>28,729</td>
<td></td>
<td>541,021</td>
</tr>
</tbody>
</table>


## Community Essential Functions Example

- Workers to ensure continuity of building functions, including but not limited to security and environmental controls (e.g., HVAC), building transportation equipment, the manufacturing and distribution of the products required for these functions, and the permits and inspections for construction supporting essential infrastructure.

- Elections personnel to include both public and private sector elections support.

- Workers supporting the operations of the judicial system, including judges, lawyers, and others providing legal assistance.

- Workers who support administration and delivery of unemployment insurance programs, income maintenance, employment services, vocational rehabilitation programs and services, disaster assistance, workers’ compensation insurance and benefits programs, and pandemic assistance.


- Trade Officials (FTA negotiators; International data flow administrators).

- Workers who support radio, print, internet and television news and media services, including, but not limited to front line news reporters, studio, and technicians for newsgathering, reporting, and publishing news.

- Workers supporting Census 2020.

- Weather forecasters.

- Clergy and other essential support for houses of worship.

- Workers who maintain digital systems infrastructure supporting other critical government operations.

- Workers who support necessary permitting, credentialing, vetting, certifying, and licensing for essential critical infrastructure workers and their operations.

- Customs and immigration workers who are critical to facilitating trade in support of the national emergency response supply chain.

- Workers at testing and education centers for emergency medical services and other healthcare workers.

- Staff at government offices who perform title search, notary, and recording services in support of mortgage and real estate services and transactions.

- Residential and commercial real estate services, including settlement services.

- Workers supporting essential maintenance, manufacturing, design, operation, inspection, security, and construction for essential products, services, supply chain, and COVID-19 relief efforts.

- Workers performing services to animals in human care, including zoos and aquariums.

- Engineers performing or supporting safety inspections.

- Veterinary nurses, technicians, veterinarians, and other services supporting individuals and organizations with service animals, search and rescue dogs, and support animals.

- Workers providing dependent care services, including childcare, eldercare, and other service providers necessary to maintain a comprehensive, supportive environment for individuals and caregivers needing these services.
Other considerations that factor into operational plans: feasibility

• Adults 65+
  • Transportation challenges, throughput in typical vaccine sites
  • High intent to receive vaccine
  • High public support for persons aged 65+/elderly to receive priority vaccination

• Essential workers
  • Rural, shift workers, multiple jobs, small cohorts
  • Onsite or pharmacy or health dept POD teams
  • High public support for essential workers (i.e., police/fire/rescue and teachers)

• Adults with high-risk medical conditions
  • LARGE group, how to determine eligibility (without violating HIPAA or privacy)
  • High public support for priority vaccination of this group
<table>
<thead>
<tr>
<th>Ethical Principle</th>
<th>Older Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age 75+ years (21M)</td>
</tr>
<tr>
<td></td>
<td>Age 65-74 Years (32M)</td>
</tr>
<tr>
<td>Maximize benefits and minimize harms</td>
<td>Reduces morbidity and mortality in persons with <strong>highest</strong> burden of COVID-19 hospitalization and death</td>
</tr>
<tr>
<td>Promote justice</td>
<td>- Will require focused outreach to those who experience barriers to access healthcare</td>
</tr>
<tr>
<td>Mitigate Health inequities</td>
<td>- Racial and ethnic minority groups under-represented among adults ≥65</td>
</tr>
<tr>
<td>Ethical Principle</td>
<td>Frontline essential workers (~30 M) / Other essential workers (~57M)</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Maximize benefits and minimize harms**| - Essential Workers are at high risk of exposure. Prevention of disease will reduce transmission  
  - Preserves services essential to the COVID-19 response and overall functioning of society. “Multiplier effect” |
| **Promote justice**                      | - Workers unable to work from home  
  - High level of interaction with public or others in the workplace  
  - May be unable to control social distancing |
| **Mitigate Health inequities**           | - Racial and ethnic minority groups disproportionately represented in many essential industries  
  - ~1/4 of essential workers live in low-income families  
  - Frequently interact with others in the workplace |
<table>
<thead>
<tr>
<th>Ethical Principle</th>
<th>Persons 16-64 with high-risk medical conditions (&gt;110 Million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximize benefits and minimize harms</td>
<td>Reduces morbidity and mortality in persons with <strong>moderate to high</strong> burden of COVID-19 associated hospitalization and death</td>
</tr>
<tr>
<td>Promote justice</td>
<td>Will require focused outreach to those with limited or no access to healthcare</td>
</tr>
</tbody>
</table>
| Mitigate Health inequities             | - Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas  
                                          - Diagnosis of medical conditions requires access to healthcare |
Summary: Work Group considerations

- Scientific, implementation and ethical considerations support inclusion of groups in Phase 1b and 1c as a balance of prevention of morbidity and mortality and preservation of societal functions.
- This represents an interim Phase 1 sequence—allocation policy will need to be dynamic and adapt as new information such as vaccine performance and supply and demand become clear.
- Gating criteria will be necessary to move expeditiously from one Phase to the next, if supply exceeds demand.
- Following vaccination, measures to stop the possible spread of SARS-CoV-2, such as masks and social distancing, will still be needed.
- The U.S. government is committed to making COVID-19 vaccines available to all residents, as soon as possible.

Example of Phase 1 & Phase 2 COVID-19 vaccination roll-out
ACIP Vote – Interim Recommendation

As an update to ACIP recommendations for vaccination in Phase 1a (health care personnel, and long-term care facility residents), if COVID-19 vaccine supply is limited, the following groups should be offered vaccination:

Phase 1b: persons aged ≥75 years and frontline essential workers
Phase 1c: persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and other essential workers
Healthcare personnel: Stage 1A
(12/1/20 ACIP recommendation)

- Residents = health care personnel
- 1A also includes staff (incl fellows and faculty) and residents (patients) in
  - Long-term care facilities
  - Assisted Living
  - Community Care Homes
  - Foster Homes
- DOH, Health systems and UH still working on details
- Health professions students in clinical settings – also Stage 1A (~January)
Essential Staff Prioritization Process Flow – 1b

1. **Organizations Designate Priority for Staff to Receive Vaccine**
   - HDOH provides general guidance to enable prioritization

2. **Organizations Identify Doses Needed Based on Recommended Criteria**

3. **Hawaii Department of Health Allocates Doses**
   - Allocations based on CDC allotment by week and operational/logistical considerations
   - HDOH provides guidance on where/how essential workers will get vaccinated

4. **Hawaii Department of Health Notifies Organizations of Allotment**
   - Organizations notify and schedule staff based on allotment
Practical considerations and challenges – day 5

- # of doses logistics through HHIEM and DOH
- Hospitals making adjustments; decide on their own processes
- Neighbor islands will look differently
- Splitting the Pfizer 975 dose- shipments to hospitals
- Moderna arrives today – State/County POD
- Messaging to pregnant/breastfeeding women
- CDC “Pre-Vaccination Form”
- DOH Screening/Assent form for State/County PODs
- Time of administration/waiting time
- Data entry (VAMS)
- Post-vaccine monitoring at vaccination site
- V-SAFE (individual level)
- VAERS
- Hawai‘i Immunization Registry
What about non-hospital affiliated 1A/1B?

- UH working with DOH to consider POD
  - UHP clinics
  - Health Profession students who are not volunteer vaccinators
  - Other first responders besides CCHNL (Leeward CC Dec 22-30)
  - BSL2+
  - Older UH essential workers

- **Operational needs informed by weekly shipments of vaccine**

- Independent provider survey

- Hospitals considering capacity for other non-affiliated but are still refining details regarding 1A
  - Some further subprioritizing may be needed

- QMC-WO partnered with WCCHC

Stay Tuned. Coming Soon!